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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/383,745	08/26/1999	MARIA ALEXANDRA GLUCKSMANN	5800-8A	6988

826 7590 12/14/2001

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EXAMINER	
LAZAR WESLEY, ELIANE M	
ART UNIT	**PAPER NUMBER**
1646	14

DATE MAILED: 12/14/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/383,745	Applicant(s) Glucksmann
	Examiner Eliane Lazar-Wesley	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 9, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *32-59* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *32-59* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The amendment filed October 09, 2001, has been entered.

2. New claims 32-59 are under consideration.

Claim Rejections - 35 USC § 101/112

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 32-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are to methods of modulating the activity of a polypeptide of SEQ ID No:1 or variants thereof, using a compound, and to methods of identifying a compound that modulates the activity of the polypeptide or variants thereof.

Applicants disclose the nucleic acid and deduced amino acid sequence of a "14926 receptor", that they describe as being a G-protein coupled receptor (GPRC), based upon structural motifs characteristic of other GPRC, or a hydrophibicity plot (Figures 2 and 4, for example). While

this assumption would be credible for one of skill in the art, applicants do not provide a specific utility for the claimed "14926 receptor", as for example no ligand for the receptor and no specific function for the receptor are disclosed. Applicants do not provide a specific utility for the claimed "14926 receptor", as for example no ligand for the receptor, no specific function for the receptor, and no specific and substantial signaling activity or cellular response are disclosed. The gene and the protein of the invention are disclosed, page 3, lines 28-31, as being useful as targets and reagents in receptor assays applicable to treatment and diagnostic of (yet undefined) GPRC-mediated disorders. However, this constitutes an invitation to experiment and an invitation to use the gene and encoded protein as a research tool, but does not provide at the present time a specific and well established utility. We are in the situation of testing a polypeptide of unknown function with an unknown ligand, and of using the polypeptide as a research tool for finding a ligand and finding out which signaling or response are triggered by activation, or which disease is involved in the activation of the potential receptor. Applicants do not provide a specific and well established utility providing patentability for their invention. The invention therefore does not fulfill the requirements of 35 USC 101.

Applicants argue that 14926 encodes a G-protein coupled receptor. However, these arguments are not to the point, as the Examiner does not reject the claims under the grounds that 14926 could not encode a G-protein coupled receptor. In fact, the Examiner recites in the rejection that " this assumption would be credible for one of skill in the art", and the rejection applies to the lack of a specific and well-established utility providing a patentable use for the invention. What

is challenged is not that 14926 might be a G-protein coupled receptor, but rather than at the time the application was filed, appellants have not provided a specific and substantial utility for the gene. Reciting that 14926 encodes a G-protein coupled receptor does not provide a specific, substantial and well established utility, as G-protein coupled receptors belong to a large family of receptors having very different ligands and functions, like for example serotonin receptors, adrenergic receptors, dopamine receptor and muscarinic acetylcholine receptor, (see Stadel, TiPS 18:430-437, 1997, cited by Applicants) and different signaling mechanisms. The fact that 14926 has structural motifs similar to known G-protein coupled receptors does not provide for a specific, substantial and well-established utility, but rather is a starting point or a hint for further research aimed at defining what the utility of the gene could be.

Applicants argue that 14926 has specific, substantial and credible utility, because those of skill in the art recognize that the identification of a novel member of the G-protein coupled receptor family provides an immediate benefit in serving as reagents and targets in the diagnosis and treatment of 14926-mediated disorders, and in selectivity screening of candidate drugs that target GPCRs. This is not found persuasive, because there is no link disclosed between the instant 14926 gene and any disorder, as discussed in the rejection, and because the use in selectivity screening actually means that the instant 14926 requires further research to have a specific and substantial utility. As discussed supra, the gene and the protein of the invention are disclosed, page 3, lines 28-31, as being useful as targets and reagents in receptor assays applicable to treatment and diagnostic of (yet undefined) GPRC-mediated disorders. However, this constitutes an

invitation to experiment and an invitation to use the gene and encoded protein as a research tool, but does not provide at the present time a specific and well established utility, because using a receptor of unknown function and unknown ligand to target unknown drugs for an unknown disease, does not provide a patentable utility for the invention, but merely constitutes an invitation to experiment and perform further research. Applicants provide examples, at page12, to show proteins whose functions have been determined based on sequence homology, but this is in fact in agreement with the Examiner's position, which is that the sequence homology was used as a starting point for further research aimed at defining what the utility of the gene could be.

Applicants argue that the 14926 receptor shares a high degree of identity with the rhodopsin family of GPCRs, especially the serotonin receptor family, and therefore has a specific, immediately available, real world utility in the selectivity screening of drugs. This is not found persuasive, as shown by Stadel, TiPS 18:430-436, 1997, cited by Applicants, that points to the fact, at page 434, first column, last paragraph, that "The reverse molecular pharmacology strategy is a far more daunting challenging and risky endeavour when compared with the more traditional approach, since the starting material for a drug discovery effort is simply an orphan receptor of unknown function, with no apparent relationship to a disease indication". Serving in selectivity screening is not a specific utility, because it does not rely on a particular characteristic of the instant 14926 gene, but rather relies on features shared by many diverse GPCRs.

6. Claims 32-59 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention and which activity to measure.

Furthermore, claims 52, 54, 56, 58, and their dependent claims, recite a step of assessing the activity of the polypeptide, and the specification does not disclose which activity to measure in the case of the claimed polypeptide, neither which signaling or response are triggered by activation of the polypeptide and could be measured to assess the activity of the instant polypeptide.

Applicants arguments have been addressed in the rejection under 35 USC 101, above.

7. Claims 37-46, 54-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 37, 42, 54, 56 are to sequence variants of the amino acid of SEQ ID No:1. Applicants do not disclose such variants, nor do they teach which parts of the polypeptide of SEQ ID No:1 is essential for the activity of the polypeptide, or which mutations in the polypeptide will be tolerated for maintaining the function. Applicants do not convey that they were in possession of the invention at the time of filing.

Applicants argue that they have described the variants by their structural properties and their functional properties. However, this is not found persuasive, because the specification does not disclose which mutations or substitutions would be tolerated for keeping an activity, and it is well known in the art that single mutations in GPCRs modify their activity, as shown for example by Stadel in Table 2 . Furthermore, the specific function of the polypeptide has not been provided, as discussed supra. It is well knownin the art that single mutations in GPCRs modify their activity, as shown for example by Stadel in Table 2.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 42-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 37, 42 and 47 , and their dependent claims, are indefinite and confusing, as they recite " to modulate the activity of the polypeptide to thereby modify the activity of the polypeptide", which is either redundant or refers to different polypeptides, wherein only the polypeptide of SEQ ID No:1 appears in the preamble.

Claim 37 is also confusing because it is not clear what is meant by "wherein the activity of the polypeptide is modulated is in a cell".

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

December 13, 2001

ELW

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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